K040611

JUN 0 4 2004

BIOMET

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Manufacturing Corp.
56 Bell East Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Patricia Sandborn Beres
Telephone: (574) 267-6639

Proprietary Name: Modular Radial Head Replacement Device

Common Name: Elbow hemi-prosthesis

Classification Name: Elbow joint radial (hemi-elbow) polymer prosthesis (21 CFR 888.3170)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed: Liverpool Radial Head Replacement Device (K012551), Radial Head Surface Replacement (Implex Corp. K984290), Radial Head Implant (Avanta Orthop., Inc., K002644) and Modular Radial Head (Wright Medical Tech. Inc., K991915)

Device Description: The Modular Radial Head Replacement Device is a two-piece prosthesis consisting of a stem (Ti-6Al-4V) and a head (Co-Cr-Mo). The tapered stem is cemented into the intramedullary canal of the radius. The head has a highly polished concave surface to articulate with the natural bone of the humerus and ulna. The proximal portion of the stems are roughened with a Bond Coat surface. The components connect via a dove-tail joint secured by a locking screw. The device is available in three diameters, 18mm, 20mm and 22mm with head heights that vary from 8 to 20mm. Stems are available in six diameters with varying lengths.

Intended Use: The Modular Radial Head Replacement Device is intended for:

1) Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, creptation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
    a) Joint destruction and/or subluxation visible on x-ray
    b) Resistance to conservative treatment
2) Primary replacement after fracture of the radial head
3) Symptomatic sequelae after radial head resection
4) Revision following failed radial head arthroplasty

The device is intended for single use with bone cement.

Summary of Technologies: The technological characteristics (materials, design, sizing, and indications) of the Modular Radial Head Replacement Device are similar to or identical to the predicate devices.

Non-Clinical Testing and Clinical Testing: none provided as a basis of substantial equivalence

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 4 2004

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K040611
Trade/Device Name: Modular Radial Head Replacement Device
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: II
Product Code: KWI
Dated: March 5, 2004
Received: March 8, 2004

Dear Ms. Sandborn Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

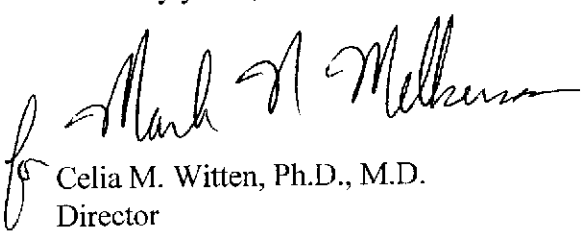
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040611

Device Name: Modular Radial Head Replacement Device

Indications For Use: The Modular Radial Head Replacement Device is intended for:

1) Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, creptation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
   a) Joint destruction and/or subluxation visible on x-ray
   b) Resistance to conservative treatment
2) Primary replacement after fracture of the radial head
3) Symptomatic sequelae after radial head resection
4) Revision following failed radial head arthroplasty

The device is intended for single use with bone cement.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040611